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SECTION 5, 510(k) Summary

Company Information:

Smiths Medical ASD, Inc.
201 West Queen Street
Southington, CT 06489
Registration Number: **1219611**

Contact: Brian D. Farias
Regulatory Affairs Manager
(603) 352-3812, ext 2493

Summary Prepared: December 15, 2011

Product Name:

Trade Name: **ViaValve™ Safety I.V. Catheter**

Common Name: Peripheral I.V. Catheter

Classification Name: 880.5200 Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days

Predicate Device(s):

K990236 (ProtectIV® and ProtectIV® Plus Safety I.V. Catheter) - Marketed by Smiths Medical ASD, Inc.

K110443 (BD Insyte™ Autoguard™ BC Shielded I.V. Catheter) - Marketed by Becton Dickinson (BD) & Co.

Device Description:

The ViaValve™ Safety I.V. Catheter provides access to a vein or artery. The ViaValve™ Safety I.V. Catheter incorporates a valve inside the catheter hub which is designed to reduce blood exposure during initial catheter placement. The valve will open and allow flow once the Luer connector is attached and will remain open after initial activation. The needle assembly incorporates a needle guard which locks over the needle as the ViaValve™ Safety I.V. Catheter is threaded into the vessel to help reduce the risk of accidental needlesticks.

Indications for Use:

A properly placed ViaValve™ Safety I.V. Catheter provides access to a vein or artery to sample blood, monitor blood pressure, or administer fluids. The needle guard locks over the needle as the catheter is threaded into the vessel to help reduce the risk of accidental needlesticks. These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. 18 to 24 gauge catheters may be used with power injectors up to 300 PSI.

Technological Characteristics:

The ViaValve™ Safety I.V. Catheter is a peripheral intravascular catheter with a valve and integral needlestick protection. The valve inside the ViaValve™ Safety I.V. Catheter hub is designed to reduce blood exposure upon initial catheter placement and is equivalent to the blood control feature of the predicate BD Insyte™ Autoguard™ BC catheter. The needle guard employs the same technology as the Smiths Medical predicate ProtectIV® Plus Catheter and locks over the needle as the ViaValve™ Safety I.V. Catheter is threaded.

Non-Clinical Data:

Bench testing and ISO standard compliance testing confirms that the ViaValve™ Safety I.V. Catheter and the predicate devices have similar performance specifications based on the applicable standards for I.V. catheters and FDA Guidance *"Medical Devices with Sharps Injury Prevention Features" August 9, 2005* for medical devices with sharps injury prevention features.

Clinical Data:

Simulated clinical use studies were conducted which confirmed that the ViaValve™ Safety I.V. Catheter could be used safely and effectively with the needle shielded by the needle guard after use.

Human Factors Engineering (HFE) and Usability testing was conducted. Analysis of the validation results concluded that the ViaValve™ Safety I.V. Catheter was adequately safe and effective for its intended users, uses and use environments.

Conclusion:

The bench testing, standards compliance testing, simulated clinical use, and HFE validation studies conducted demonstrate that the ViaValve™ Safety I.V. Catheter is safe and effective and is Substantially Equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Brian Farias
Regulatory Affairs Manager
Smiths Medical ASD, Inc.
201 West Queen Street
Southington, Connecticut 06489

MAR 1 4 2012

Re: K113700
Trade/Device Name: ViaValve™ Safety I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 15, 2011
Received: December 16, 2011

Dear Mr. Farias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113700

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: **ViaValve™ Safety I.V. Catheter**

Indications for Use:

A properly placed ViaValve™ Safety I.V. Catheter provides access to a vein or artery to sample blood, monitor blood pressure, or administer fluids. The needle guard locks over the needle as the catheter is threaded into the vessel to help reduce the risk of accidental needlesticks. These catheters may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused, and duration of therapy. 18 to 24 gauge catheters may be used with power injectors up to 300 PSI.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Richard C Chapman 3/17/12

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K113700